REMARKS

Claims 1 – 7 and 9 – 36 are pending. Claims 1, 5 – 7, 9, 12, 13, 17, 18, 22 – 25, 27 – 31, and 36 are amended, claims 33 and 34 are withdrawn from consideration, and claims 8, 10, 11, 16, 19, 20, and 35 are cancelled. Upon entry of the amendment claims 1 – 7, 9, 12 – 15, 17, 18, 21 – 34, and 36 will be pending.

Support for the Amendments

Support for the amendments is found, for example, throughout the specification and claims as originally filed. For example, support for the amendment of claims 1 and 18, which now recites "reducing motorneuron loss associated with amyotrophic lateral sclerosis (ALS)" is found at page 33, lines 7-9; support for amendment of claims 1, 5 – 7, 9, 12, 13, 17, 18, 22 – 25, 27 – 31, and 36, which now recite "ceftriaxone or a salt thereof" is found, for example, at page 4, lines 11-13; and support for the amendment of claim 1, which now recites that ceftriaxone is administered for "a time period exceeding three weeks" is found, for example, at page 24, lines 16-18. No new matter has been added by virtue of the amendments,

Specification

The Examiner objects to the specification because it contains sequence disclosures (in particular the sequence listing filed on April 21, 2006) and fails to comply with 37 C.F.R. §§ 1.821 – 1.825.

Applicants note that the specification and drawings were amended on January 18, 2007 to remove the sequences in Figure 1 and the references to the sequences in the specification. Applicants have amended the specification to delete the sequence listing. As amended, the specification does not contain a sequence disclosure and, therefore, complies with 37 C.F.R. §§ 1.821 – 1.825.

Claim Objections

Claim 16 is objected to for not reciting "of" between "consisting" and "Parkinson's." Applicants have cancelled claim 16, thereby obviating the objection.

Rejections under 35 U.S.C. § 112, first paragraph

Claims 1 – 7, 9 – 10, 14 – 19, 21 – 32, and 36 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement. Specifically, the Examiner alleges that the specification does not enable the use of all beta-lactam compounds to treat ALS. In further support of the enablement rejection, the Examiner alleges that Applicants have not enabled a "clinically effective amount" of ceftriaxone. Applicants respectfully disagree. Nevertheless, without acquiescing to the basis of the rejection and solely to advance prosecution, Applicants have amended the claims, thereby obviating these bases for the enablement rejection. Applicants respectfully request that it be withdrawn.

Rejections under 35 U.S.C. § 112, second paragraph

Claims 1 – 7, 9 – 32, and 36 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for reciting the term "substantial." As described above, claims 1 and 18, from which claims 2-7, 9-17, and 19-32 depend, are amended. The amendment deletes the term "substantial," thereby obviating the rejection.

Claim 6 is rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for reciting the term "at least about 6 months." Applicants have amended claim 6 to recite "at least 6 months," thereby obviating the rejection.

Claims 7 and 28 – 30 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for reciting the phrase "less than about" a specified dosage. Applicants have amended claims 7 and 28 – 30 to recite "less than" a specified dosage, thereby obviating the rejection.

Claim 9 is rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for reciting "does not exceed about 10." Applicants have amended claim 9 to recite "does not exceed 10," thereby obviating the rejection.

Rejections under 35 U.S.C. §103

Claims 1 – 7, 9-32, and 36 are rejected under 35 U.S.C. § 103(a) as allegedly being obvious over one or more of the following references: Koppel (U.S. Patent Application Publication No. US2004/0014739 (herein after "Koppel")), in view of Miller et al. (*Neurology*, vol. 47 (Suppl. 2), S86-90 (hereinafter "Miller")); Bristol et al. (Ann. Neurol., vol. 39, pages 676-679 (hereinafter "Bristol")); Smith (The Lancet, vol. 339, page 1417); and Khanna et al. (U.S. Patent No. 5,869,649). For the reasons detailed below, Applicants respectfully disagree with the rejections. Nevertheless, without acquiescing to the basis of the rejection and solely to advance prosecution, Applicants have amended the claims.

As amended claim 1 is directed to:

> A method of reducing motorneuron loss associated with amyotrophic lateral sclerosis (ALS) in a subject, the method comprising administering to the subject for a time period exceeding three weeks a therapeutic amount of ceftriaxone or a salt thereof which is sufficient to reduce motorneuron loss.

Koppel is directed to **methods for modulating behavior** (e.g., anxiolytic and aggressive behavior) in a subject by administering **clavulanic acid** (Abstract). Koppel fails to teach or suggest methods for reducing motor neuron loss associated with ALS in a subject using ceftriaxone. None of the other references, alone or in any combination, remedies the deficiency of Koppel.

Miller is directed to the treatment of ALS using riluzole. Bristol, as characterized by the Examiner, teaches that a defect in glutamate transport is observed in ALS (Office action, pages 20-21). As characterized by the Examiner, Khanna describes a disodium salt hemiheptahydrate of ceftriaxone.

With regard to Smith, the Examiner indicates that "Smith teaches . . . that ceftriaxone can be utilized to improve (ALS) (Office action, page 24)." However, Smith is inoperative because the same author in later report admits that the original report was inaccurate (L. G. Smith, 1992, Ceftriaxone is ineffective in ALS, The Lancet, vol. 340, page 379 (submitted herewith)). Thus, the combined references by Smith actually teach away from using Ceftriaxone for the treatment of ALS. In sum, none of the cited references, either individually or in combination, teach or suggest a

method of reducing motorneuron loss associated with ALS comprising administering a therapeutic amount of ceftriaxone to a subject. Accordingly, Applicants respectfully request that the rejections be withdrawn.

CONCLUSION

Applicants believe that the amendments herein put the claims in condition for allowance. Should the Examiner wish to discuss any of the amendments and/or remarks made herein, the undersigned attorney would appreciate the opportunity to do so.

The Commissioner is hereby authorized to charge any fees that may be required, or credit any overpayment to Deposit Account No. 04-1105.

In view of the above amendment, applicant believes the pending application is in condition for allowance.

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Respectfully submitted,
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